

Supplemental
Notice of Allowability

Application No.

10/024,678

Examiner

Blessing M. Fubara

Applicant(s)

YANG ET AL.

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview with attorney on 07/27/05.
2. ☒ The allowed claim(s) is/are 1-3, 5, 8-22, 24-45, 47-68, 70 and 126-128 (claims are renumbered).
3. ☒ The drawings filed on 18 December 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 07/27/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
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Art Unit: 1618

DETAILED ACTION

1. Applicants' election without traverse of Group I in the reply filed on 04/23 led to the withdrawal of claims 18-22, 24-45, 47-68 and 70 from consideration. However, the election requirement is withdrawn upon the allowance of the generic claims. Therefore, claims 18-22 are no longer withdrawn from consideration since claims 18-22 depend from or otherwise include each of the limitations of an allowed generic claim. Previously withdrawn claims 24-45, 47-68 and 70 are also hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 24 and 47 are amended to direct that the biocompatible polymer and the cross-linking composition be administered to the tumor from separate containers, wherein a first container comprises the biocompatible polymer and a second container comprises the cross-linking composition. Claims 25, 28, 31, 32, 38, 48, 51, 54, 55 and 61 are also amended. Claims 27, 29, 30, 50, 52 and 53 are canceled. The amendment to the claims follows below.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa L. Sistrunk on 07/27/05.

Art Unit: 1618

The application has been amended as follows:

In the claims:

Replace claim 24 with amended claim 24 as below:

Claim 24 (Currently Amended) A method of treating a tumor *in situ* in an individual comprising the steps of administering to said tumor a polymer composition that comprises a biocompatible polymer, a cross-linking composition that comprises a cross-linker, and a therapeutic agent, wherein the biocompatible polymer and the cross-linking composition are administered to allow formation of a cross-linked polymer *in situ* at the tumor, which cross-linked polymer comprises the therapeutic agent, and wherein the biocompatible polymer and the cross-linking composition are administered to the tumor from separate containers, wherein a first container comprises the biocompatible polymer and a second container comprises the cross-linking composition.

Replace claim 25 with the amended claim 25 as below:

Claim 25 (Currently Amended) The method of claim 24, wherein the biocompatible polymer comprises the therapeutic agent.

Cancel claim 27

In claim 28, delete "27" and insert ---24---

Cancel claim 29

Cancel claim 30

In claim 31, delete "30" and insert ---26---

Replace claim 32 with the amended claim 32 as below:

Claim 32 (Currently Amended) The method of claim 24, wherein the polymer composition and cross-linking compositions are administered separately from a syringe having at least two compartments, said compartments further defined as said separate containers.

Replace claim 38 with the amended claim 38 as below:

(Claim 38 Currently Amended) The method of claim 36, wherein said salt of a divalent cation is tin chloride, calcium chloride, calcium sulfate, calcium phosphate, calcium carbonate, calcium chlorate, calcium fluoride, calcium bromide, magnesium chloride, magnesium sulfate, magnesium phosphate, magnesium carbonate, magnesium chlorate,

Art Unit: 1618

magnesium fluoride, magnesium bromide, manganese chloride, manganese sulfate, manganese phosphate, manganese carbonate, manganese chlorate, manganese fluoride, manganese bromide, copper chloride, copper sulfate, copper phosphate, copper carbonate, copper chlorate, copper fluoride, copper bromide, chromium chloride, chromium sulfate, chromium phosphate, chromium carbonate, chromium chlorate, chromium fluoride, chromium bromide, strontium chloride, strontium sulfate, strontium phosphate, strontium carbonate, strontium chlorate, strontium fluoride, strontium bromide, zinc chloride, zinc sulfate, zinc phosphate, zinc carbonate, zinc chlorate, zinc fluoride, zinc bromide, radium chloride, radium sulfate, radium phosphate, radium carbonate, radium chlorate, radium fluoride, radium bromide, beryllium chloride, beryllium sulfate, beryllium phosphate, beryllium carbonate, beryllium chlorate, beryllium fluoride, or beryllium bromide.

Replace claim 47 with amended claim 47 as below:

Claim 47 (Currently Amended) A method of occluding an artery associated with a tumor in an individual comprising the step of administering to said tumor a polymer composition that comprises a biocompatible polymer and a cross-linking composition that comprises a cross-linker, wherein the biocompatible polymer and the cross-linking composition are administered to allow formation of the cross-linked polymer *in situ* at the tumor, wherein the biocompatible polymer and the cross-linking composition are administered to the tumor from separate containers, wherein a first container comprises the biocompatible polymer and a second container comprises the cross-linking composition.

Replace claim 48 with amended claim 48 as below:

Claim 48 (Currently Amended) The method of claim 47, wherein the biocompatible polymer further comprises a therapeutic agent.

Cancel claim 50

In claim 51, delete "50" and insert ---47---

Cancel claim 52

Cancel claim 53

In claim 54, delete "53" and insert ---49---

Replace claim 55 with the amended claim 55 as below:

Art Unit: 1618

Claim 55 (Currently Amended) The method of claim 47, wherein the polymer composition and cross-linking compositions are administered separately from a syringe having at least two compartments, said compartments further defined as said separate containers.

Replace claim 61 with the amended claim 61 as below:

Claim 61 (Currently Amended) The method of claim 59, wherein said salt of a divalent cation is tin chloride, calcium chloride, calcium sulfate, calcium phosphate, calcium carbonate, calcium chlorate, calcium fluoride, calcium bromide, magnesium chloride, magnesium sulfate, magnesium phosphate, magnesium carbonate, magnesium chlorate, magnesium fluoride, magnesium bromide, manganese chloride, manganese sulfate, manganese phosphate, manganese carbonate, manganese chlorate, manganese fluoride, manganese bromide, copper chloride, copper sulfate, copper phosphate, copper carbonate, copper chlorate, copper fluoride, copper bromide, chromium chloride, chromium sulfate, chromium phosphate, chromium carbonate, chromium chlorate, chromium fluoride, chromium bromide, strontium chloride, strontium sulfate, strontium phosphate, strontium carbonate, strontium chlorate, strontium fluoride, strontium bromide, zinc chloride, zinc sulfate, zinc phosphate, zinc carbonate, zinc chlorate, zinc fluoride, zinc bromide, radium chloride, radium sulfate, radium phosphate, radium carbonate, radium chlorate, radium fluoride, radium bromide, beryllium chloride, beryllium sulfate, beryllium phosphate, beryllium carbonate, beryllium chlorate, beryllium fluoride, or beryllium bromide.

Allowable Subject Matter

3. The following is an examiner's statement of reasons for allowance: Delmotte et al. (US 5,989,215) does not administer to a localized region a composition that comprises a polymer, a cross-linking agent and a therapeutic agent. Fick (US 5,945,100) does not disclose administering a cross-linking composition and a polymer composition from different vessels/containers to a localized site where cross-linking of the polymer takes place in situ. The pending claims are thus allowable.


Art Unit: 1618


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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